

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1201 Veterinary Prescription Drugs
SPONSOR(S): Paul
TIED BILLS: None. **IDEN./SIM. BILLS:** CS/SB 1824 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care		Garner	Collins
2) Health Appropriations (Sub)			
3) Appropriations			
4)			
5)			

SUMMARY ANALYSIS

In 2003, the Legislature passed the Pharmaceutical Drug Protection Act (CS/CS/SB 2312, Ch. 2003-155, Laws of Florida), in response to a Statewide Grand Jury report indicating that there is widespread diversion, adulteration and/or counterfeiting of prescription drugs in Florida. Among the many provisions of the 2003 law, the act requires that all wholesale distributors post a \$100,000 bond; have at least one employee who has training in federal and state prescription drug laws and rules; and requires liability insurance.

Under the act, all wholesale prescription drug distributors must obtain a permit pursuant to the Florida Drug and Cosmetic Act, ch. 499, F.S., either as a prescription drug wholesaler, or if located outside of Florida, as an out-of-state prescription drug wholesaler. The current law makes no distinction between wholesalers of prescription drugs designed for human consumption versus those who distribute prescription drugs meant only for animal consumption. As a result, veterinary prescription drug wholesalers must comply with the same requirements as wholesalers of prescribed drugs for human consumption, which affects veterinary drug wholesalers to a greater extent.

HB 1201 changes the permitting requirement for wholesalers of veterinary prescription drugs, separating them from the permitting requirements of wholesale distributors of prescription drugs meant for human consumption. The bill provides a fee for the permit which may not be less than \$300 or more than \$500 annually. The bill expressly exempts "veterinary prescription drugs" from the definition of "wholesale distributor," and provides the Department of Health (DOH) the regulatory authority to inspect the records of a person permitted to sell veterinary drugs. HB 1201 expands the regulatory role of the DOH to allow the department to examine, sample, seize, and stop the sale or use of a veterinary prescription if the department determines that the drug represents a threat to public safety.

The Department of Health (DOH) states that because the fee range in the bill for veterinary prescription drug wholesalers is lower than the current fee for prescription drug wholesalers, there will be a reduction in revenues to the DOH. An estimated 10 companies that only distributes veterinary prescription drugs will be required to convert to this new permit type given the limited parameters in the bill, so the reduction in revenue will be minimal.

The bill provides an effective date of July 1, 2004.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h1201.hc.doc
DATE: March 22, 2004

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|---|-----------------------------|---|
| 1. Reduce government? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a "no" above, please explain:

B. EFFECT OF PROPOSED CHANGES:

HB 1201 changes the permitting requirement for wholesalers of veterinary prescription drugs, separating them from the permitting requirements of wholesale distributors of prescription drugs meant for human consumption. The bill provides a fee for the permit which may not be less than \$300 or more than \$500 annually. The bill expressly exempts "veterinary prescription drugs" from the definition of "wholesale distributor," and provides the Department of Health (DOH) the regulatory authority to inspect the records of a person permitted to sell veterinary drugs. HB 1201 expands the regulatory role of the DOH to allow the department to examine, sample, seize, and stop the sale or use of a veterinary prescription if the department determines that the drug represents a threat to public safety.

PRESENT SITUATION

The Pharmaceutical Drug Protection Act

The Department of Health (DOH), Bureau of Statewide Pharmaceutical Services, is responsible for regulating the wholesale distribution of both regular and veterinary prescription drugs in Florida. The Bureau of Statewide Pharmaceutical Services has primary responsibility for implementing the Pharmaceutical Drug Protection Act.

In 2003, the Legislature passed the Pharmaceutical Drug Protection Act (CS/CS/SB 2312, Ch. 2003-155, L.O.F.), in response to a Statewide Grand Jury report indicating that there is widespread diversion, adulteration and/or counterfeiting of prescription drugs in Florida. Among the many provisions of the 2003 law, the act requires that all wholesale distributors post a \$100,000 bond; have at least one employee who has training in federal and state prescription drug laws and rules; and requires liability insurance.

Under the act, all wholesale prescription drug distributors must obtain a permit pursuant to the Florida Drug and Cosmetic Act, ch. 499, F.S., either as a prescription drug wholesaler, or if located outside of Florida, as an out-of-state prescription drug wholesaler. The current law makes no distinction between wholesalers of prescription drugs designed for human consumption versus those who distribute prescription drugs meant only for animal consumption. As a result, veterinary prescription drug wholesalers must comply with the same requirements as wholesalers of prescribed drugs for human, which affects veterinary drug wholesalers to greater extent.

At the current time, the Department of Health states that these provisions of the Pharmaceutical Drug Protection Act apply to 10 wholesalers who exclusive distribute veterinary drugs.

C. SECTION DIRECTORY:

Section 1. Provides a definition of “veterinary prescription drug wholesaler.”

Section 2. Requires a person or establishment to obtain a permit in order to operate as a veterinary prescription drug wholesaler.

Section 3. Provides that the distribution of veterinary prescription drugs is not included within the meaning of the terms "wholesale distribution" or "wholesale distributor" of prescription drugs.

Section 4. Requires an annual fee for a veterinary prescription drug wholesaler's permit.

Section 5. Requires the Department of Health to inspect veterinary prescription drug wholesale establishments; and authorizes the department to close such establishment if it creates an imminent danger to the public health.

Section 6. Provides an effective date of July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Department of Health (DOH) states that because the fee range in the bill for veterinary prescription drug wholesalers is lower than the current fee for prescription drug wholesalers, there will be a reduction in revenues to the DOH. An estimated 10 companies that only distributes veterinary prescription drugs will be required to convert to this new permit type given the limited parameters in the bill, so the reduction in revenue will be minimal.

Estimated Revenues	Year 1	Year 2
Decrease in permit fee collections		
$(\$800-\$500=\$300) \times 4 = \$1,200$	\$1,200	\$1,200
$(\$700-\$500=\$200) \times 6 = \$1,200$	1,200	1,200
Total Estimated Loss of Revenue	\$2,400	\$2,400

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

According to the Department of Health, establishments that are currently permitted as prescription drug wholesalers or out-of-state prescription drug wholesalers that qualify for this permit because they only deal in veterinary prescription drugs and only sell to animal health entities will save the costs associated with providing a \$100,000 refundable bond each year, the cost of fingerprinting (\$47 per

person) and will have a reduced application fee – an annual decrease of either \$300 or \$200, respectively. Additionally, these establishments will complete a much simpler application form, which will result in reduced administrative costs to them.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the Department of Health the necessary rulemaking authority needed to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

- The Department of Health (DOH) General Counsel's Office (HGC) reports that they believe the bill conflicts with ss. 492.012, F.S. and 492.0121, F.S., that regulate the wholesale distribution of veterinary legend drugs, as well as being internally inconsistent. Currently, ch. 499, F.S., protects animal health by subjecting the wholesalers of veterinary legend drugs to stringent regulation to prevent the diversion of such drugs from regulated channels. This bill, while creating a new permit category for veterinary prescription drug wholesalers, exempts the distribution of veterinary legend drugs from the definition of wholesale distribution, and thereby from the particular regulations in current law pertaining to all legend drug wholesalers which protect animal health.
- The DOH has also had cases where veterinary legend drugs that are controlled substances were sold to unauthorized sources that ultimately sold them for human use [abuse]. This bill would not prohibit such actions, thereby potentially providing less of a deterrent to substance abuse.
- A strike everything amendment will be offered to conform HB1201 to CS/SB 1824.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES